

We claim:

1. A method of treating human immunodeficiency virus (HIV) in a mammal comprising administering to a mammal in need thereof a therapeutically effective amount of nelfinavir or
5 a pharmaceutically acceptable salt or solvate thereof in a pharmaceutical composition at least once daily for at least two weeks, wherein at least once daily the nelfinavir is administered with food and the food comprises more than 800 kcal.
2. The method of claim 1, wherein the food comprises more than about 900 kcal.
- 10 3. The method of claim 1, wherein the food comprises more than about 1000 kcal.
4. The method of claim 1, wherein the administration of nelfinavir occurs between 30 minutes prior to and two hours after consumption of food.
- 15 5. The method of claim 1, wherein the administration of nelfinavir occurs between 30 minutes prior to and one hour after consumption of food.
6. The method of claim 1, wherein the administration of nelfinavir occurs at about the
20 same time as the consumption of food.
7. The method of claim 1, wherein nelfinavir is administered at least twice daily for at least two weeks and at least twice daily nelfinavir is administered with food and the food comprises more than 800 kcal at each administration.
- 25 8. The method of claim 1, wherein the food comprises between about 40% fat and about 50% fat by energy content.
9. The method of claim 1, wherein the food comprises between about 50% fat and
30 about 60% fat by energy content.
10. The method of claim 1, wherein the food comprises between about 60% fat and about 70% fat by energy content.
- 35 11. The method of claim 1, wherein the food comprises between about 70% fat and about 80% fat by energy content.

12. The method of claim 1, wherein the food comprises between about 80% fat and about 90% fat by energy content.

13. The method of claim 1, wherein the food comprises between about 90% fat and about 100% fat by energy content.

14. The method of claim 1, wherein the food comprises more than 40% fat by energy content.

15. The method of claim 1, wherein the food comprises more than about 50% fat by energy content.

16. The method of claim 1, wherein the food comprises more than about 60% fat by energy content.

17. The method of claim 1, wherein the food comprises more than about 70% fat by energy content.

18. The method of claim 1, wherein the food comprises more than about 80% fat by energy content.

19. The method of claim 1, wherein the food comprises more than about 90% fat by energy content.

20. The method of claim 1, wherein the food comprises from 36 g to 55 g fat.

21. The method of claim 1, wherein the food comprises from 40 g to 55 g fat.

22. The method of claim 1, wherein the food comprises at least about 55 g fat.

23. The method of claim 1, wherein the area under the curve from time zero extrapolated to infinite time ($AUC(0-\infty)$) after nelfinavir administration with food is at least about 3-fold greater than the $AUC(0-\infty)$ after administration in the fasted state.

24. The method of claim 23, wherein the $AUC(0-\infty)$ after nelfinavir administration with food is at least about 5-fold greater than the $AUC(0-\infty)$ after administration in the fasted state.

25. The method of claim 1, wherein the mammal is not receiving ritonavir, saquinavir or lopinavir or a stereoisomer, solvate, salt, or prodrug thereof.

5 26. A method of treating human immunodeficiency virus (HIV) in a mammal comprising administering orally to a mammal in need thereof a therapeutically effective amount of nelfinavir or pharmaceutically acceptable salt or solvate thereof in a pharmaceutical composition taken with food, wherein the food comprises at least about 500 kcal and at least about 50% fat by energy content.

10

27. The method of claim 26 wherein the administration of nelfinavir occurs between 30 minutes prior to and two hours after consumption of food.

15 28. The method of claim 26, wherein the administration of nelfinavir occurs between 30 minutes prior to and one hour after consumption of food.

29. The method of claim 26, wherein the administration of nelfinavir occurs at about the same time as the consumption of food.

20 30. The method of claim 26, wherein the food comprises between about 50% fat and about 60% fat by energy content.

31. The method of claim 26, wherein the food comprises between about 60% fat and about 70% fat by energy content.

25

32. The method of claim 26, wherein the food comprises between about 70% fat and about 80% fat by energy content.

30 33. The method of claim 26, wherein the food comprises between about 80% fat and about 90% fat by energy content.

34. The method of claim 26, wherein the food comprises between about 90% fat and about 100% fat by energy content.

35 35. The method of claim 26, wherein the food comprises more than about 60% fat by energy content.

36. The method of claim 26, wherein the food comprises more than about 70% fat by energy content.
37. The method of claim 26, wherein the food comprises more than about 80% fat by energy content.
38. The method of claim 26, wherein the food comprises more than about 90% fat by energy content.
39. The method of claim 26, wherein the food comprises from 36 g to 55 g fat.
40. The method of claim 26, wherein the food comprises from 40 g to 55 g fat.
41. The method of claim 26, wherein the food comprises at least about 55 g fat.
42. The method of claim 26, wherein the food comprises at least about 600 kcal.
43. The method of claim 26, wherein the food comprises at least about 700 kcal.
44. The method of claim 26, wherein the food comprises at least about 800 kcal.
45. The method of claim 26, wherein the food comprises at least about 900 kcal.
46. The method of claim 26, wherein the food comprises at least about 1000 kcal.
47. The method of claim 26, wherein the area under the curve from time zero extrapolated to infinite time ($AUC(0-\infty)$) after nelfinavir administration with food is at least about 3-fold greater than the $AUC(0-\infty)$ after administration in the fasted state.
48. The method of claim 47, wherein the $AUC(0-\infty)$ after nelfinavir administration with food is at least about 5-fold greater than the $AUC(0-\infty)$ after administration in the fasted state.
49. The method of claim 26, wherein the mammal is not receiving ritonavir, saquinavir or lopinavir or a stereoisomer, solvate, salt, or prodrug thereof.

50. A method of treating human immunodeficiency virus (HIV) in a mammal comprising administering to a mammal in need thereof a therapeutically effective amount of nelfinavir or a pharmaceutically acceptable salt or solvate thereof in a pharmaceutical composition at least once daily for at least two weeks, wherein at least once daily nelfinavir is taken with
5 food and the food comprises more than about 500 kcal and more than about 50% fat by energy content.

51. The method of claim 50, wherein the administration of nelfinavir occurs between 30 minutes prior to and two hours after consumption of food.
10

52. The method of claim 50, wherein the administration of nelfinavir occurs between 30 minutes prior to and one hour after consumption of food.

53. The method of claim 50, wherein the administration of nelfinavir occurs at about the same time as the consumption of food.
15

54. The method of claim 50, wherein nelfinavir is administered at least twice daily for at least two weeks and at least twice daily nelfinavir is administered with food and the food comprises more than 500 kcal and more than about 50% fat by energy content at each
20 administration.

55. The method of claim 50, wherein the food comprises more than about 600 kcal.

56. The method of claim 50, wherein the food comprises more than about 700 kcal.
25

57. The method of claim 50, wherein the food comprises more than about 900 kcal.

58. The method of claim 50, wherein the food comprises more than about 1000 kcal.

59. The method of claim 50, wherein the food comprises between about 50% fat and about 60% fat by energy content.
30

60. The method of claim 50, wherein the food comprises between about 60% fat and about 70% fat by energy content.
35

61. The method of claim 50, wherein the food comprises between about 70% fat and about 80% fat by energy content.

62. The method of claim 50, wherein the food comprises between about 80% fat and about 90% fat by energy content.

5 63. The method of claim 50, wherein the food comprises between about 90% fat and about 100% fat by energy content.

64. The method of claim 50, wherein the food comprises more than about 60% fat by energy content.

10

65. The method of claim 50, wherein the food comprises more than about 70% fat by energy content.

15 66. The method of claim 50, wherein the food comprises more than about 80% fat by energy content.

67. The method of claim 50, wherein the food comprises more than about 90% fat by energy content.

20 68. The method of claim 50, wherein the food comprises from 36 g to 55 g fat.

69. The method of claim 50, wherein the food comprises from 40 g to 55 g fat.

70. The method of claim 50, wherein the food comprises at least about 55 g fat.

25

71. The method of claim 50, wherein the mammal is not receiving ritonavir, saquinavir or lopinavir or a stereoisomer, solvate, salt or prodrug thereof.

30 72. The method of claim 50, wherein the area under the curve from time zero extrapolated to infinite time ($AUC(0-\infty)$) after nelfinavir administration with food is at least about 3-fold greater than the $AUC(0-\infty)$ after administration in the fasted state.

35 73. The method of claim 72, wherein the $AUC(0-\infty)$ after nelfinavir administration with food is at least about 5-fold greater than the $AUC(0-\infty)$ after administration in the fasted state.

74. The method of claim 50, wherein the mammal is not receiving ritonavir, saquinavir or lopinavir or a stereoisomer, solvate, salt, or prodrug thereof.

5 75. A kit comprising a therapeutically effective oral dose of nelfinavir and a printed material comprising instructions for administering the dose with food comprising at least 800 kcal in a high-fat meal.

76. The kit of claim 75, wherein the label further comprises instructions for administering the dose with food comprising at least 50% fat by energy content.

10

77. The kit of claim 75, wherein the high-fat meal is recited to comprise more than about 36 g of fat.

15 78. A therapeutic composition for the treatment of human immunodeficiency virus (HIV) in a mammal comprising fat and a therapeutically effective amount of nelfinavir in a weight ratio of at least about 25 fat:1 nelfinavir.

79. The composition of claim 78, wherein the weight ratio is greater than about 30 fat:1 nelfinavir.

20

80. The composition of claim 78, wherein the amount of nelfinavir is between about 100 mg and about 1500 mg.